

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Neuromobilization on Pain, Range of motion, Muscle Endurance and Disability in Cervical Radiculopathy, A Randomized Controlled Trial

Protocol summary

Study aim

To determine the effect of neuromobilization in cervical radiculopathy as this is cost effective treatment.

Design

A double blinded randomized controlled trial

Settings and conduct

Physiotherapy department of Mayo hospital Lahore Punjab, Pakistan. IRB Approved

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age group between 35-50 years . Gender both male and female. Subjects having radiating symptoms of cervical radiculopathy . Subjects with no previous cervical surgeries . Subjects with no loss of the upper limb movement. Exclusion criteria: Subjects having traumatic history . Subjects with Osteoporosis . Hypermobile patients . Subjects with circulatory disturbances . Subjects with peripheral nerve entrapment . Subjects with tumor causing cervical radiculopathy . Patients who are not willing to be included in the study.

Intervention groups

(Experimental group): A neural mobilization technique with sliding of median nerve will be applied with 3 seconds hold in each repetition In this group conservative treatment which will include cervical isometrics exercises with 10 repetitions in each direction with 5 seconds hold will also be given. Isometric exercises will be performed with the patient in sitting position. (control group): Conservative treatment will be given which will include cervical isometrics exercises with 10 repetitions in each direction with 5 seconds hold will also be given. Isometric exercises will be performed with the patient in sitting position 3 sets of these exercises will be performed with the rest period of 30seconds. All the subjects will be given hot packs for 10 minutes prior to the treatment.

Main outcome variables

Range of motion measured by inclinometer, Pain intensity

measured by visual analogue scale, Muscle endurance by craniocervical flexion test, Disability by neck disability index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043109N1**

Registration date: **2019-06-30, 1398/04/09**

Registration timing: **prospective**

Last update: **2019-06-30, 1398/04/09**

Update count: **0**

Registration date

2019-06-30, 1398/04/09

Registrant information

Name

shazia rafiq

Name of organization / entity

University of Lahore

Country

Pakistan

Phone

+92 42 99200600

Email address

shazesarfraz@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2640-06-22, 2019/04/01

Expected recruitment end date

2641-12-21, 2020/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Neuromobilization on Pain, Range of motion, Muscle Endurance and Disability in Cervical Radiculopathy, A Randomized Controlled Trial

Public title
Effectiveness of Neuromobilization in neck pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age group between 35-50 years Gender both male and female Subjects having radiating symptoms of cervical radiculopathy Subjects with no previous cervical surgeries Subjects with no loss of the upper limb movement
Exclusion criteria:
Subjects having traumatic history Subjects with Osteoporosis Hypermobility patients Subjects with circulatory disturbances Subjects with peripheral nerve entrapment Subjects with tumor causing cervical radiculopathy Patients who are not willing to be included in the study.

Age
From **35 years** old to **50 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Outcome assessor
- Data analyst

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: Randomization sequence will be created by using Excel 2016 with a 1:1 allocation using simple randomization by an independent researcher who will not be participating in treatment of patients. Patients will be allocated to two groups by concealment of allocation through sealed envelopes. Concealment of allocation: Allocation concealment will be achieved with sequentially numbered, opaque, sealed, envelopes SNOSE. SNOSE will be used according to guidelines of Doig and Simpson 26. An independent researcher with no clinical involvement in the trial will make the concealed envelopes. 88 Envelopes will be made. Half envelopes will contain folded papers with Treatment A written on them and the remaining half will contain folded papers with Treatment B written on them. A carbon paper will be inserted in each envelope with carbon side facing the paper so the allocation sequence, patient name, date of

birth of participant and other information can be transferred onto allocation paper inside the envelope. A piece of tin foil is also inserted into envelope so the treatment card cannot be read against light. Envelopes will be sealed and signed by the maker. A unique randomized number will be allocated to these envelopes and shuffled vigorously. Then the envelopes will be arranged sequentially and handed over to another independent researcher. 28 Assessor will pretest the participant and if eligible envelope will be allocated to subject. Therapist will record the information on the envelope and open it afterwards to maintain the concealment. Assessor will record the post treatment findings and another independent analyst will analyze the data. This allocation of concealment will ensure the unpredictability of treatment allocation by investigators and patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding: In this study patients, assessors, data analysts will be blinded to allocation of treatment groups in this study. Except for the therapist all other staff will be kept blinded as they will not be informed about the details of allocation. Trial will be adhered to established procedures to maintain separation between staff who will collect outcome measurements and the therapist. Patient will be blinded to treatment allocation as treatment will be given in separate rooms for each group. Therapist who is not blinded will not take the outcome measurements. All the other assessors, investigators and analysts will not know the details of treatment.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board, University of Lahore

Street address

Raiwind Road

City

Lahore

Postal code

53720

Approval date

2639-11-11, 2018/08/20

Ethics committee reference number

IRB-UOL-FAHS/373-VI/2018

Health conditions studied

1

Description of health condition studied

Patients suffering from cervical rediculopathy leading decrease their input in all type of activities they are unable to coop with their daily routine due to pain and decrease range of motion their quality of life impaired.

ICD-10 code

M50.1

ICD-10 code description

Cervical disc disorders

Primary outcomes

1

Description

Pain

Timepoint

Pre assessment will be done at baseline, second assessment will be done after 2 weeks and final post assessment will be done at the end of 12th session in 4th week

Method of measurement

Pain by Visual analogue scale

2

Description

Range of motion

Timepoint

Pre assessment will be done at baseline, second assessment will be done after 2 weeks and final post assessment will be done at the end of 12th session in 4th week

Method of measurement

Range of motion will be measured by Inclinator

3

Description

Muscle endurance

Timepoint

Pre assessment will be done at baseline, second assessment will be done after 2 weeks and final post assessment will be done at the end of 12th session in 4th week

Method of measurement

By Cranio Cervical flexion test

4

Description

Neck Disability

Timepoint

Pre assessment will be done at baseline, second assessment will be done after 2 weeks and final post assessment will be done at the end of 12th session in 4th week

Method of measurement

Neck disability index

5

Description

Quality of life

Timepoint

Pre assessment will be done at baseline, second assessment will be done after 2 weeks and final post assessment will be done at the end of 12th session in 4th week

Method of measurement

SF 36 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A (Experimental group): In group A neural mobilization technique with sliding of median nerve will be applied with 3 seconds hold in each repetition, Neural mobilization will be done according to technique described by David Butler. Subject will be placed in supine position and slider neural mobilization of the median nerve will be given. In this group conservative treatment which will include cervical isometrics exercises with 10 repetitions in each direction with 5 seconds hold will also be given. Isometric exercises will be performed with the patient in sitting position.

Category

Treatment - Other

2

Description

Control group: Group B (control group): In group B conservative treatment will be given which will include cervical isometrics exercises with 10 repetitions in each direction with 5 seconds hold will also be given. Isometric exercises will be performed with the patient in sitting position 3 sets of these exercises will be performed with the rest period of 30seconds. All the subjects will be given hot packs for 10 minutes prior to the treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mayo Hospital Lahore

Full name of responsible person

Nighat Ansar

Street address

Near Neela Gunbad Anarkali Bazar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University Of Lahore
Full name of responsible person
Shazia Rafiq
Street address
Raiwind Road
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53270
Phone
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Email
shazesarfraz@gmail.com
Grant name
N/A
Grant code / Reference number
N/A
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University Of Lahore
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
The University Of Lahore
Full name of responsible person
Umair Ahmed
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Neuro Rehab

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Shazia Rafiq
Position
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Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Shazia Rafiq
Position
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Latest degree
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Other areas of specialty/work
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Province
Punjab
Postal code
53720
Phone

N/A

Email

shazesarfraz@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

EFFECTIVENESS OF NEURO MOBILIZATION ON PAIN, RANGE OF MOTION, MUSCLE ENDURANCE AND DISABILITY IN CERVICAL RADICULOPATHY: A RANDOMIZED CONTROLLED TRIAL.

When the data will become available and for how long

Data will be available when my Ph.D Study completed

To whom data/document is available

For academic institutions only

Under which criteria data/document could be used

People who will request for data

From where data/document is obtainable

Through email address

What processes are involved for a request to access data/document

My email address

Comments

N/A